



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration/Xavier University Global Outsourcing Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled “FDA/Xavier University Global Outsourcing Conference.” This public conference for the pharmaceutical industry is in direct alignment with the “FDA Strategic Priorities 2011-2015,” and includes presentations from key FDA officials, global regulators, and industry experts. This conference drives collaboration on the topic of global outsourcing compliance by bringing pharmaceutical/ biotechnology companies and contract partners to the same event to address the issues that reside on both sides of the contract. Expert presentations address the “how to” aspects of improving outsourced product quality through topics such as FDA International Initiatives, FDA Inspection Trends, Supply Chain Development, Quality Agreements, Supplier Qualification, and many more. The experience level of our audience has fostered engaged dialogue that has led to innovative initiatives.

Dates and Times: The public conference will be held on September 24, 2012, from 8:30 a.m. to 5 p.m.; September 25, 2012, from 8:30 a.m. to 5:30 p.m.; and September 26, 2012, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

Contact Persons:

For information regarding this notice: Steven Eastham, Food and Drug Administration, Cincinnati South Office, 36 East Seventh Street, Cincinnati, OH 45202, 513-246-4134, email: [steven.eastham@fda.hhs.gov](mailto:steven.eastham@fda.hhs.gov).

For information regarding the conference and registration: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: [phillipsm4@xavier.edu](mailto:phillipsm4@xavier.edu).

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 2 1/2 days of the conference. Early registration ends August 5, 2012. Standard registration ends September 2, 2012. Late registration occurs September 3 to September 23, 2012. There will also be onsite registration. The cost of registration is as follows:

Attendee	Fee on or before August 5th	Fee August 6th–September 2nd	Fee September 3rd–September 23rd
Industry	\$995	\$1,295	\$1,495
Small Business (<100 employees)	\$800	\$900	\$1,000
Consultants	\$500	\$600	\$700
Startup Manufacturers/Academic	\$200	\$250	\$300
Media/Government	Free	Free	Free

<sup>1</sup>The fourth registration from the same company is free.

The following forms of payment will be accepted: American Express, Visa, Mastercard, and company checks.

To register online for the public conference, please visit the “Register Now” link on the conference Web site at <http://www.XavierGOC.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.

To register by mail, please send your name, title, firm name, address, telephone and fax numbers, email, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513-421-9100. To make reservations online, please visit the “Venue & Logistics” link at <http://www.XavierGOC.com> to make reservations. The hotel is expected to sell out during this timeframe, so early reservation in the conference room-block is encouraged.

If you need special accommodations due to a disability, please contact Marla Phillips (see Contact Persons) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services and FDA’s important mission to protect the public health. The conference will provide those engaged in FDA-regulated outsourcing with information on the following topics:

- FDA International Initiatives
- European Union Regulator Perspective
- United States Pharmacopeia Chapter Development Impact
- Total Cost of Quality

- FDA New Inspectional Approach and Trends
- Supplier Selection and Due Diligence
- How to Operate in Different Regions of the World
- Establishing a Meaningful Supplier Qualification Program
- Supply Chain Development
- Finished Product Distribution Channel
- Enterprise Resource Planning
- Self Inspections & Corporate Audits
- Quality Agreements
- Business Process Management
- Global Standards Association Near Term Solutions

The conference includes:

- Deep Dive Lunch Sessions
- Live Polling Used by Speakers
- Case Studies
- Small Group Discussions
- Networking Lunch by Topic

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of

1996 (Public Law 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-17077 Filed 07/12/2012 at 8:45 am; Publication Date: 07/13/2012]